# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



| Applicant's or agent's file reference<br>526875C:RDC | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
|---|---|---|
| International Application No.<br>**PCT/AU2003/001458** | International Filing Date *(day/month/year)*<br>6 November 2003 | Priority Date *(day/month/year)*<br>15 November 2002 |
| International Patent Classification (IPC) or national classification and IPC<br>**Int. Cl.** [7] A61M 1/10 | | |
| Applicant<br>SUNSHINE HEART COMPANY PTY LTD et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| I | ☒ | Basis of the report |
| II | ☐ | Priority |
| III | ☐ | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | ☒ | Lack of unity of invention |
| V | ☒ | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | ☐ | Certain documents cited |
| VII | ☐ | Certain defects in the international application |
| VIII | ☒ | Certain observations on the international application |

| Date of submission of the demand<br>8 June 2004 | Date of completion of the report<br>7 March 2005 |
|---|---|
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br>**SWAYAM CHINTAMANI**<br>Telephone No. (02) 6283 2202 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
**PCT/AU2003/001458**

## I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

## IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   For details see supplemental box 1.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | **1-80** | **YES** |
| | Claims | | **NO** |
| Inventive step (IS) | Claims | **1-80** | **YES** |
| | Claims | | **NO** |
| Industrial applicability (IA) | Claims | **1-80** | **YES** |
| | Claims | | **NO** |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 6471633 B1
D2 US 4051840 A
D3 US 4630597 A
D4 US 4979936 A
D5 WO 2002/024254 A2
D6 WO 2000/076288 A2
D7 US 4583523 A
D8 US 6030336 A
D9 US 6045496 A
D10 WO 2002/024255 A1

Novelty (N)

Although the citations D1 to D10 are identified as X category documents in the International Search Report, a close scrutiny of these documents revealed that none of the documents teaches all the features of each of the claims. Therefore claims 1-80 are novel subject to the lack of descriptive support objections in section VIII.

D1 teaches a dynamic aortic patch that is sutured into the descending aorta. The document does not teach a method of installing the patch into an ascending aorta. The document does not teach the stretching of an opening formed by resecting an aortic wall. The document does not include a device having a motive means to periodically actuate and de-actuate the aortic compression means in counter-pulsation with the patient's heart rhythm.

Similarly, each of the documents D2 to D4 also teaches an aortic patch for implanting in a descending aorta.

D5 teaches a counter pulsation blood circulation assistance device installed on an ascending aorta in figure 10. But the device completely surrounds the ascending aorta and thus differs from the current application. Although one of the embodiment shown in figure 5 and described on page 18 in D5 teaches a device having an inflatable cuff and bladder having a shape of around 270 degrees of arc of a circle.

D6 teaches a heart assist device having an inflatable cuff that partly encircles the ascending aorta. See claim 6 and figures 1a and 1b.

D7 discloses an aorta compressing device having a motive device with gripping portions partially surrounding the aorta. In an alternative embodiment the aorta is wrapped in a protective bandage.

***Continued on supplemental box 2.***

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. When all of the claims are considered together, one cannot understand the scope of the monopoly being claimed because it is not readily clear what combination of integers defines the invention. This is because different claims have different combinations of integers.
2. The term "a portion of the circumference of the aorta", in general in all claims, needs to be more clearly defined in view of the large number of related prior art documents. Particularly the term "a portion" is open ended and includes within its meaning any portion of the circumference ranging from 1 to 359 degrees. Therefore all the claims which have this term define an invention that is not fairly based on what is described at lines 11-13 on page 2 and at lines 17-20 on page 6 of the specification. The referred passages in the description and the figures suggest that the invention is directed at a part of the circumference that is less than 180 degrees. No such limitation is indicated in the claims.
3. Each of the claims 11, 15, 48, 50-53, 56, 57 and 68 do not define the invention. The claims omit the limitation on the portion of the circumference covered by the device which appears to be essential to the invention

**Supplemental Box 1**
(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of IV**

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions.

When all of the claims are considered together, it is not clear what combination of integers defines the invention. This is because different claims have different combinations of integers.

1. Claims 11-32, 54 and 56 require resection of the aorta while claims 1-10, 33-53, 55, 57-80 involve extra-aortic counter pulsation. The device of the first group applies compressive force directly on the blood, while the second group defines a device that applies compressive force to a portion of the vessel.

2. Claims 48, 50 and 53 define a device that can be used to apply compressive forces on any artery, while some claims are limited to (a) ascending aorta or (b) descending aorta which require different devices due to their location and geometry. This is contrary to the stated objective (see page 2 lines 20-23) of solving the prior art disadvantage.

3. The devices of claims 48 and 51-54 restricted by a special geometry on the depression generated or the deflated part of the balloon.

4. Some claims, such as claim 40, are restricted to compress only a portion of the circumference, while others devices are not clearly restricted to "only a portion".

5. Claim 50 defines a device that can compress aorta substantially without stretching or bunching. While the device of claim 48 causes the artery to flex along a continuous line, which increases in length as the counterpulsation pressure applied to the artery increases.

The above list is not exhaustive. Because of a large number of special technical features and due to different combinations of integers the international application does not relate to one invention or to a single inventive concept

**Supplemental Box 2**
(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of V**

D8 teaches a pressure generator/regulator device for an implantable heart assist pump of the back-pressure balloon, an intra-aortic device and thus teaches away from the invention.

D9 discloses an occluder device having a tube that completely surrounds the aorta. See figure 9 and the related description at lines 31-47 in column 10.

D10 teaches a heart assist device including a flexible hollow inflatable cuff curved along its length and having two free ends adapted to overlap when the cuff is placed around the aorta.

Claim 1 is distinguished over the prior art by the feature of installing a heart assist device extending around a portion of the circumference of an ascending aorta.

Thus none of the above documents teaches a device as defined in claims 40-80.

None of these documents teaches all the combination of steps defined in claims 1-39.

Inventive Step (IS)

The claimed invention is not obvious in the light of any of the cited documents nor is it disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.